

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BOARD OF REGENTS, THE UNIVERSITY  
OF TEXAS SYSTEM, and TISSUEGEN,  
INC.,

*Plaintiffs,*

v.

BOSTON SCIENTIFIC CORPORATION,

*Defendant.*

Case No. 18-392-GBW

**BOSTON SCIENTIFIC CORPORATION'S RESPONSE IN OPPOSITION TO  
PLAINTIFFS' MOTION TO STRIKE TESTIMONY AND FOR A  
LIMITING INSTRUCTION**

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DATED: January 30, 2023

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## I. INTRODUCTION

Boston Scientific Corporation (“Boston Scientific”) respectfully requests that the Court deny Plaintiffs’ Motion to Strike Testimony and For a Limiting Instruction Regarding Boston Scientific’s Arguments on the Method of Manufacturing a Fiber, (D.I. 320; the “Motion”). Plaintiffs’ Motion—filed just yesterday after 4:00PM, without conferring with counsel for Boston Scientific or otherwise providing any notice—effectively seeks to exclude the testimony of Boston Scientific’s expert, Dr. Mooney, concerning his opinion that the Synergy stents lack a “fiber” as that term has been construed by the Court. (Motion at 10.) According to Plaintiffs, “Dr. Mooney intentionally, repeatedly and pervasively communicated to the jury that a fiber as claimed . . . must be made via a spinning process” in contravention of this Court’s prior orders. (Motion at 5.) Plaintiffs’ accusations are without merit and their motion should be denied.

As a threshold matter, Dr. Mooney could not have been more clear, Claim 1 of the ’296 patent is not limited to a method of manufacture:

Q. The patent claim is not -- the patent claim is not limited to a particular process?

A. *Nope, it’s not.*

(Trial Tr. at 805:3-14.)<sup>1</sup>

Dr. Mooney’s testimony concerning example processes that may be used to form polymer fibers was fully consistent with this Court’s prior Orders. Indeed, *Plaintiffs’ own witnesses* testified extensively about processes for making polymers into fibers, including spinning and extrusion processes. To the extent the witnesses have disagreements over which types of processes are suitable for making a fiber, those are simply factual disputes. Nothing more.

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<sup>1</sup> All emphasis added unless otherwise indicated.

Moreover, Plaintiffs' counsel *never objected*—at any time—to the substance of Dr. Mooney's testimony as it was being presented and any such objections are therefore waived. If Plaintiffs' counsel believed the testimony was problematic, they had every opportunity to object, including at multiple sidebars. Plaintiffs also never raised any issue with Dr. Mooney's testimony at the conclusion of the trial day, despite raising a myriad of other issues. Instead, Plaintiffs waited two days to raise the issue, by filing this motion without notice after 4:00PM on Sunday, January 29, 2023. Accordingly, while Plaintiffs' motion has no merit, their objections are also not timely and are waived.

## **II. NATURE AND STAGE OF THE PROCEEDINGS**

Trial in this case commenced on January 25, 2023.

## **III. SUMMARY OF THE ARGUMENT**

1. Plaintiffs have waived any challenge as to the substance of Dr. Mooney's testimony by failing to raise any timely objections to that testimony while it was being presented at trial, despite multiple opportunities to do so.

2. Dr. Mooney's testimony fully complies with the Court's Orders—indeed, Dr. Mooney was clear that Claim 1 of the '296 patent *is not* limited by a method of manufacturing.

3. Dr. Mooney's testimony concerning examples of manufacturing methods that he is aware of for forming polymer fibers is consistent with the Court's prior Orders. Indeed, Plaintiffs' own witnesses similarly testified about methods of manufacturing polymer fibers, including “spinning” or “extrusion” processes.

4. To the extent Plaintiffs disagree with Dr. Mooney's examples of methods of manufacturing polymer fibers, this is simply a factual dispute.

5. Plaintiffs' motion has no merit, and there is no basis for their accusations of coaching, intentional violations of Court orders, or other misconduct.

#### IV. STATEMENT OF FACTS

On November 17, 2022, the Court, in its mini-*Markman* Order, acknowledged that Boston Scientific “has stated multiple times before this Court that it does not limit its construction to a method of manufacturing.” (D.I. 255 at 17.) As such, the Court declined to “effectively import a manufacturing process into the definition of ‘fiber’ based on extrinsic evidence alone by requiring a fiber to have a common orientation.” (D.I. 255 at 17.)

On December 20, 2022, Plaintiffs submitted their Motion *In Limine* No. 3 that sought to “exclude all references to past claim construction positions by either party’s experts.” (D.I. 263-17.) Plaintiffs’ motion was granted-in-part and denied-in-part. (D.I. 276.). Relevant to the present dispute, the Court found that neither Boston Scientific nor its expert may assert “that Claim 1 of [the ’296 patent] is limited by a method of manufacturing.” (D.I. 276 at 1-2.) However, as the Court made clear during the final pretrial conference hearing, “Boston Scientific may argue that the accused products manufacturing process causes its polymer coating not to form a thread-like structure.” (D.I. 288 at 65:12-14.) Trial in this case began on January 25, 2023.

#### V. LEGAL STANDARD

The exclusion of critical evidence at trial is an “extreme sanction” that is normally reserved for a “showing of willful deception or ‘flagrant disregard’ of a court order by the proponent of evidence.” *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (quoting *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 905 (3d Cir. 1977)). This is because “[c]redibility determinations, the weighing of evidence, and the drawing of legitimate inferences from the facts are jury functions.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

In addition, it is well-settled that a party may waive an objection by failing to timely raise the objection at trial. *See* Fed. R. Evid. 103. “The requirement of a timely objection promotes judicial economy by enhancing the trial court’s ability to remedy the asserted error. If a party fails

to object in a timely fashion, the objection is waived.” *Gov’t of Virgin Islands v. Archibald*, 987 F.2d 180, 184 (3d Cir. 1993) (citations omitted); *United States v. Gibbs*, 739 F.2d 838, 849 (3d Cir. 1984) (en banc) (objection untimely where it was made it “not when the evidence was offered, but during a motion to strike made after the [other party] rested”); *see also Grace v. Mauser-Werke GmbH*, 700 F.Supp. 1383, 1388 (E.D. Pa. Nov. 28, 1988).

## VI. ARGUMENT

### A. Plaintiffs Have Waived Any Objection to Dr. Mooney’s Testimony By Failing to Timely Object at Trial.

Plaintiffs waived their objections by failing to timely raise them at trial. Plaintiffs’ counsel never objected at any point at trial to Dr. Mooney’s testimony concerning example fiber manufacturing processes.<sup>2</sup> (*See* Trial Tr. at 674:25-742:1 (no objections as to substance).) If Plaintiffs had an issue with Dr. Mooney’s testimony, they had every opportunity to object, including through sidebars if necessary. Indeed, Plaintiffs’ counsel *did ask* for a sidebar during Dr. Mooney’s testimony concerning the “immiscibility” limitation. Plaintiffs’ failure to do so for any of Dr. Mooney’s testimony concerning “fibers” only highlights their waiver of any objections. Plaintiffs’ counsel also did not raise any issue with Dr. Mooney’s testimony at the conclusion of the trial day, despite raising a number of other issues. Having failed to raise any objection during Dr. Mooney’s testimony, Plaintiffs waived any objections. *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, No. CV 09-290, 2012 WL 12894752, at \*3 (W.D. Pa. Dec. 18, 2012) (“[C]onsistent with Third Circuit precedent, [] counsel waived the objections that it raises now in the motion to strike by not making an affirmative objection to his ultimate opinion at trial.”); *Carnegie Mellon*

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<sup>2</sup> The sole objection that occurred during the entirety of Dr. Mooney’s testimony concerning the “fiber” limitation did not even concern the substance of his answer. (*See* Trial Tr. at 719:8-16.)



*Univ. v. Marvell Tech. Grp., Ltd.*, No. CIV.A. 09-290, 2012 WL 6578412, at \*1 (W.D. Pa. Dec. 17, 2012) (objection untimely under FRE 103 where party only objected “later at the end of the day, once the jury had been dismissed for a recess”); *Gov’t of Virgin Islands*, 987 F.2d at 184 (“If a party fails to object in a timely fashion, the objection is waived.”).

There is no merit to Plaintiffs’ suggestion that “[a]n objection would have required a sidebar eating up time and it would have emphasized the testimony,” (D.I. 320 at 8 n.13), and that they had no opportunity to “object before the testimony was published,” (*id.* at 8). If Plaintiffs thought the testimony was objectionable, they should have timely objected or asked for a sidebar. Indeed, this is exactly what they did on the “immiscibility” issue—they asked for a sidebar to express objections to Dr. Mooney’s testimony, which the Court overruled. (Trial Tr. at 745:17-749:17.) Plaintiffs also could have addressed this issue after the jury was excused at the end of the day and the Court addressed other trial-related logistics. Plaintiffs did none of these things.

Plaintiffs’ silence is even more glaring when considering that Boston Scientific dedicated significant time to discussing the “fiber” term with Dr. Mooney during his direct examination. *See Carnegie Mellon Univ.*, 2012 WL 6578412, at \*2 (denying motion to strike where party “could have addressed the objection before [witness] spoke at length about” the evidence). Plaintiffs had ample opportunity to object, and their failure to do so results in waiver. *See Feesers, Inc. v. Michael Foods, Inc.*, No. 04-576, 2008 WL 4890030, at \*1 (M.D. Pa. Nov. 12, 2008) (finding objection waived and denying motion to strike where party “waited until after the exhibits and testimony were entered into evidence and [opposing party] neared the close of its case to object.”).

#### **B. Dr. Mooney’s Testimony Is In Full Compliance With the Court’s Orders.**

Dr. Mooney’s testimony is, in any event, fully consistent with the Court’s Orders. The Court’s Orders state that neither Boston Scientific nor its expert may assert “that Claim 1 of [the ’296 patent] is limited by a method of manufacturing.” (D.I. 276 at 1-2.) Dr. Mooney *never*

*testified* that Claim 1 of the '296 patent is limited by a method of manufacturing. Just the opposite. Dr. Mooney unequivocally stated that the claims were “not” limited to any particular manufacturing process. (Trial Tr. at 805:3-14.)

Dr. Mooney’s testimony about example processes that he is aware of for forming polymer fibers is similarly consistent with the Court’s prior Orders. (*See, e.g., id.* at 696:25-697:7 (discussing “examples of processes for making a fiber”; no objections); *id.* at 698:5-12 (explaining that Boston Scientific’s manufacturing process does not use the listed example processes; no objections); *id.* at 698:13-700:8 (discussing “an example of a spinning process” in conjunction with slide including image from the Encyclopedia Britannica; no objections); *id.* at 702:10-703:22 (discussing the content of a prior art reference; no objections); *id.* at 725:12-14 (explaining that Boston Scientific does not use an example process previously discussed; no objections).

Plaintiffs do not point to any testimony that violated the Court’s Order. As an initial matter, Plaintiffs conveniently ignore the fact that on cross-examination, they expressly asked Dr. Mooney whether Claim 1 is “limited to a particular process,” and that Dr. Mooney stated “*Nope, it’s not.*” (*Id.* at 805:12-14.)<sup>3</sup> Plaintiffs then point to examples of testimony from Dr. Mooney about examples of processes for making fibers, but nowhere does Dr. Mooney in any way state that Claim 1 is limited to a method of manufacturing. Dr. Mooney’s testimony instead consistently referred to “examples” of making polymer fibers, which the Court had expressly permitted Dr. Mooney to do. (*Id.* at 541:4-5 (overruling objections to Dr. Mooney’s demonstrative exhibits); *see also id.* at 7:5-15 (noting that discussion of examples “would seem to be consistent with the Court’s ruling”).)

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<sup>3</sup> This also shows how Plaintiffs can make any clarifying points on cross-examination.

Indeed, in the testimony referred to at page 8 of Plaintiffs' brief, Dr. Mooney was talking about the slide attached as Exhibit A, which is prominently titled "Some examples of processes for making a polymer fiber," and which the Court expressly allowed Boston Scientific to use in Dr. Mooney's direct examination. (Trial Tr. at 541:4-5 (overruling objection to slides 22 and 23.)) Dr. Mooney's other slides also repeatedly referred to "examples" of manufacturing processes.

Again, Dr. Mooney never stated that Claim 1 is limited to a method of manufacture, let alone any of the example processes that he discussed.

Accordingly, his testimony was in full compliance with the Court's Orders.

### **C. Plaintiffs' Own Witnesses Testified About Processes for Making Polymer Fibers.**

The appropriateness of Dr. Mooney's testimony is further shown by the fact that *Plaintiffs' own witnesses* similarly testified at length about methods of manufacturing polymer fibers.

For example, during Dr. Nelson's direct examination, he provided extensive explanation concerning fiber manufacturing processes for the jury upon questioning from Plaintiffs' counsel. (See Trial Tr. at 177:25-178:2 ("Q. how did you make the polymer fiber coils at that time? A. We made them by *a process called casting winding*."); *id.* at 3-11 (discussing how "casting winding" is performed); *id.* at 194:25-198:12 ("Q. Can you describe what you did, at a high level, to create the fibers?" . . . "A. So then I would take that emulsion *and I would extrude it*." . . . "A. So in this process, we used a – it was called *wet extrusion* . . ."); *id.* at 199:12-14 ("Q. And did you actually make fibers using this coagulation bath setup? A. Yes."); *id.* at 201:10-11 ("cylinder is depicting a *fiber that we extruded by this process* we've just described."); *id.* at 217:9-12 ("I describe a method for how you would make such a drug-rich fiber . . ."); *id.* at 218:21-219:7 (discussing "extruded" fibers); *id.* at 258:6-13 ("Q. And *how many processes did you use for making fibers, different processes*? A. Over that timeframe, three different processes. Q. *Did you ever use a*

*casting process for making fibers?* A. *Yes.* Q. Did you ever use an extrusion process for making fibers? A. Yes.”). Plaintiffs cannot reasonably dispute this—in fact, Plaintiffs’ counsel later acknowledged that “Dr. Nelson *testified about ways to make fibers in terms of his invention story*, and now I think it’s clear that this is not cumulative . . . .” (*Id.* at 808:3-7.)

Plaintiffs’ expert—Dr. Pitt—also offered extensive testimony about fiber manufacturing processes. (*See* Trial Tr. at 604:6-15 (“Q. All right. *I’m going to move to manufacturing, okay?* How many fabrication examples are there in the ’296 patent. A. *I think there are at least six.* Q. And what are some of them? A. Well, there’s example one that Dr. Nelson described where the emulsion comes into the water – or not the water, the solvent and forms a fiber. There are examples of coating a fiber layer on top of another substrate. *There’s other examples of, you know, making fibers in many ways.*”); *id.* at 607:25-608:4 (“Q. So at least between Weber, the ’296 patent, Dr. Chen, do we have at least eight [ways of making a fiber]? A. Is that a question? Q. Yes. A. Yes, the answer is yes.”); *id.* at 632:19-20 (“Q. And what does [Figure 8 of the ’296 patent] show at a high level? A. It shows one way to make a fiber.”); *id.* at 643:1-3 (“Q. And you said there are eight-plus ways, Strickler gives multiple ways as well, right, sir? A. Yes.”).)

To be sure, the Court recognized at a sidebar that counsel for Plaintiffs was questioning Dr. Pitt about fiber manufacturing processes. (*Id.* at 606:1-2 (“He’s asking about manufacturing processes. That’s what I heard.”)). In a similar vein, Dr. Pitt admitted that not all polymers are even capable of forming fibers. (*Id.* at 660:21-25 (“Q. . . . Am I right that not all polymers are fiber forming; reasonable? A. Yes.”).)

And these are just examples. The trial record is replete with evidence about manufacturing processes for polymer fibers. For example, a thesis from one of the co-inventors of the ’296 patent,

which was signed by Dr. Nelson, (DTX073.2), specifically identifies “spinning” processes for manufacturing polymer fibers:

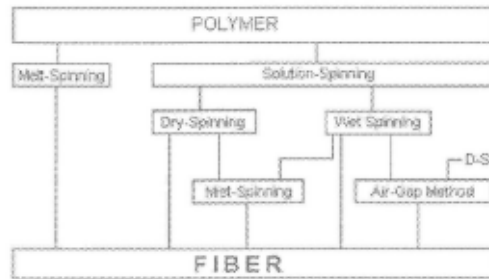


Figure 1.4. Schematic Diagram of the different fiber-fabrication techniques.

(DTX073.17). Dr. Nelson also provided testimony to that effect addressing the various examples shown therein. (Trial Tr. at 295:15-298:17.)

Here, Dr. Mooney’s testimony is no different than all of the other evidence in the trial record about processes for making polymer fibers. Each party is permitted to introduce evidence about processes for making polymer fibers. Plaintiffs did this in their case, and Boston Scientific did so in its case. To the extent the parties have disagreements over processes that are suitable for making polymer fibers, these are simply factual disputes for the jury.

#### **D. Plaintiffs Have No Basis For Their Accusations of Misconduct.**

Plaintiffs’ motion has no merit, and their accusations of misconduct are unwarranted and without basis. Plaintiffs make serious and unsupported allegations (1) that Boston Scientific has intentionally sought to “confuse and mislead the jury,” (D.I. 320 at 4), (2) that Boston Scientific is “contemptuous[ly]” violating Court orders, (*id.* at 5), (3) that Boston Scientific has “coached” Dr. Mooney to defy the Court’s orders, (*id.* at 5, n.5), (4) that Dr. Mooney “clearly intended to violate” Court orders, (*id.* at 8, n.14), (5) that this “entire line of testimony is bad faith” and

“potentially contemptuous,” (*id.* at 9), and (6) that these purported “attempts” to violate Court orders were “obviously intentional, pervasive and pre-planned,” (*id.* at 10).

Plaintiffs have no basis for these accusations. As explained above, Dr. Mooney’s testimony was in full compliance with the Court’s Orders and was also consistent with the type of testimony provided by Plaintiffs’ own witnesses. Plaintiffs also did not object to any of Dr. Mooney’s testimony in real time, did not ask for any sidebars on the matter, did not raise the issue at other sidebars, and did not raise any issues with Dr. Mooney’s testimony the end of the trial day. Instead, Plaintiffs waited two days to file this motion—on the eve of closing arguments.

**E. Plaintiffs Arguments on the Merits of Dr. Mooney’s Opinion Are Baseless and Not Relevant.**

Plaintiffs’ accusations about the accuracy of Dr. Mooney’s descriptions of Boston Scientific’s manufacturing process are similarly without merit. (D.I. 320 at 9 (“ . . . Boston Scientific’s process (that he never described accurately) . . .”); *see also id.* at 320 at 6.)<sup>4</sup> However, any dispute as to the specifics of Boston Scientific’s manufacturing process is a factual dispute for the jury to resolve. For one, the Court expressly stated that Boston Scientific “may argue that the accused products manufacturing process causes its polymer coating not to form a thread-like structure.” (D.I. 288 at 65:12-14.) Dr. Mooney provided testimony on this issue at trial. (*See* Trial Tr. at 725:7-11.)

Plaintiffs’ assert that Dr. Mooney’s testimony was “cursory at best and blatantly misrepresented [Boston Scientific’s process] as being analogous to rolling paint on a wall.” (D.I. 320 at 6.) Plaintiffs not only ignore the substance of Dr. Mooney’s testimony, but they ignore the

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<sup>4</sup> Plaintiffs’ self-serving characterizations of Boston Scientific’s manufacturing process lack any support in the record. For example, Boston Scientific is not aware of any documents describing the process as “press coating,” nor characterizing it as a “press-coating process.” (D.I. 320 at 6.)

fact that *their own expert Dr. Pitt* describes Boston Scientific's process in a nearly identical manner:

*The BSC roll-coating process is more akin to painting a surface with a roller brush* in which the paint is squeezed through a gap between the brush and wall, leaving a uniform thickness of paint. In the BSC process the roller (the stent) starts dry and runs into a pool of paint (the polymer-drug solution) on a surface and a uniform layer of material is transferred to the roller.

(D.I. 246-9 at Att. I, ¶ 6.) Plaintiffs' unfounded assertion that "Dr. Mooney concluded he did not need to study or understand the Boston Scientific process (or explain it to the jury)" is baseless. In any event, the credibility of Dr. Mooney and Dr. Pitt's descriptions of Boston Scientific's manufacturing process is an issue for the jury to decide.

## VII. CONCLUSION

For these reasons, Boston Scientific respectfully requests that the Court deny Plaintiffs' Motion and refuse to exclude any testimony provided by Dr. Mooney, and the Court need not provide any form of limiting instruction.

Dated January 30, 2023

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